

# Radiation Policy: A Decision-making Model

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Priority setting in radiation policy is complex because it depends to a large extent on risk perception. It has been shown repeatedly that the public is much more sensitive to potential harmful sequelae of radiation than to those of other environmental pollutants. Thus, cancer risk, particularly at low doses, has become a sociopolitical issue. The principle that radiation causes cancer, is life shortening, and causes an array of other pathologic disorders, is well accepted yet the quantification of sequelae at the lower end point of the dose-response curve is still controversial. The presence of a significant carcinogenic effect at very low doses has strong financial implications. Sociopolitical and economic values play a major role in the interpretation of available data. Thus, the use of nuclear energy is a function of risk/benefit, pressures, available alternatives, and cost. Three case studies—nuclear plant workers, children irradiated for an essentially benign condition, and food safety—are used to illustrate polar policy decisions. — *Environ Health Perspect* 105(Suppl 6):1599–1601 (1997)

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Health policy may be defined as a series of decision processes focusing on two issues: resource allocation and regulation (1). To make the correct decision in such a framework (which usually means a 70:30 breakdown on the average) we need data to establish priorities and compute benefit versus risk ratios.

Priority setting in radiation policy is complex because it depends to a large extent on risk perception. It has been shown repeatedly that the public is much more sensitive to potential harmful sequelae of radiation than to those of other environmental pollutants such as smoking (2). The reason for this dissonance may be that whereas self-poisoning by smoking is voluntary, radiation is attributed to the government or "the establishment" in general. Thus, cancer risk, particularly at low levels, has become a sociopolitical issue.

## Decision-making Models

The considerations involved in formulating policy may be illustrated by two sets of models. If we first consider regulation, we have four theoretical situations: ++ (positive-positive)/– – (negative-negative)/+ – (positive-negative)/– + (negative-positive) as illustrated in Figure 1.

In fact, only the upper left quadrant is involved in the decision process, as all others are irrelevant: There are no harmless substances and we are not interested in items providing no benefit.

The principle that radiation causes cancer, is life shortening, and causes an array of other pathologic disorders, is well accepted but the quantification of sequelae at the lower end point of the dose-response curve is still controversial. Therefore it is of utmost importance to have valid data on the potential hazard of low-dose radiation. Let us not forget that in contrast with the delivery of high-dose irradiation used either for severe illness or by the military,

delivery of low-dose radiation is generally under our control.

The issue of low-dose radiation carcinogenesis has come to the forefront of debate with the slowly accumulating data on excess leukemia near nuclear installations in the United Kingdom, where a significantly increased incidence of leukemia was observed in the West Berkshire area among children younger than 5 years of age and limited to an area < 10 km from the nuclear plant (3–5). Gardner et al. (6) related the excess to an apparent genetic effect through paternal exposure. Subsequent studies in other British locations and elsewhere failed to confirm this notion (7–9), which suggests that other factors such as an occasional higher radiation discharge, chemical carcinogens, or contaminated paternal clothing or dust played a much stronger role in the reported leukemogenesis than ionizing radiation. Incidentally, such an excess was noted in areas where nuclear plants were planned but never constructed (10).

Practically any regulatory process is a function of economic considerations. In our case alternate energy options are available, e.g., oil or coal. Because the presence of a significant carcinogenic effect at very low radiation doses would have strong financial implications, sociopolitical and economic values play a major role in the interpretation of available data and blur the assessment of available information. In other words, the use of nuclear energy is a function of available alternatives and cost.

Let us now consider our second policy model, which is illustrated in Figure 2.

Again, we deal with four plus and minus options but in this model all four quadrants are of interest. However, the most problematic quadrant is in the upper right. The financial deficit results primarily from the continuous technological development that strains our life system. In an era when the principles of a welfare society are often

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		Benefit	
		+	–
Harm	+		
	–		

**Figure 1.** A schematic representation of the prevailing alternatives in control of drugs, biologicals, and other health conditions.

		Resources	
		+	–
Needs	+		
	–		

**Figure 2.** A schematic representation of the prevailing alternatives in control of resource allocation.

disregarded, the missing resources must come from the apparently redundant lower left quadrant—an unworkable scenario. In a setting of this kind one must consider the construction of a Great Wall of China around each nuclear plant versus more urgent health needs such as high-tech drugs.

Then the question of who makes the decision arises. Who will face various pressure groups and make decisions that will lead to an appropriate resource allocation and enable utilization of radiation for peaceful health purposes and who is going to pay for it?

Presidents and prime ministers are rarely awakened in the middle of the night when an urgent decision bearing social implications must be made. Such decisions are usually undertaken by a lower-level official who is willing to accept the responsibility and is supported by the hierarchy, but who frequently lacks sufficient background data.

### Case Studies

I would like to illustrate the issue with two types of case studies—one in an industrial setting and the other relating to medical treatment.

There is hardly any dispute that radiation carcinogenesis has no threshold. Therefore, workers employed in nuclear energy must carry a potential, even if infinitesimal, excess risk. As radiation-induced cancer has no unique characteristics in terms of tissue or cell type, there is no way to distinguish patients who develop cancer due to the radiation treatment from those who would have developed it anyway. Thus, with increasing age the differential portion of cancer among the workers that can be attributed to radiation becomes smaller, while more persons who were irradiated in the past claim causality and compensation.

Unions, supported by interest groups, repeatedly claim compensation for individuals who develop on-the-job cancer. The employers, mostly governments, object on the basis of poor scientific support, claiming that the risk of developing cancer in middle-aged persons is due primarily to other factors. Numerous such cases are still sub judice.

The second example involves legislation based on long-term follow up of an essentially healthy irradiated population. Between 1948 and 1960, nearly 20,000 children originating from North Africa and the Middle East were treated in Israel by radiation for ringworm of the scalp as part of a widespread public health campaign to eradicate the condition. In 1965 a comprehensive investigation of the delayed effects of this X-ray therapy was initiated by our group (11).

The study cohort included 10,834 irradiated subjects, 10,834 nonirradiated population comparison subjects, and 5392 nonirradiated siblings. The mean year of irradiation was 1956 and the mean age at irradiation was 7.1 years.

Several sets of follow-up data from this population showed that the irradiated subjects had a significantly elevated risk of cancer of the head and neck, with an overall relative risk of 2. Meningiomas were outstandingly increased (relative risk > 10) (12). A dose response was demonstrated, but of particular interest was the excess of thyroid and breast cancer despite the low doses delivered to these organs (13,14).

In this particular case the government accepted responsibility for the supposedly beneficial radiation treatment that was initiated in good faith but proved detrimental. Truly, the ultimate motive for legislation might not have been devoid of political considerations. Nevertheless, each individual who can provide proof of irradiation during the period under consideration, either in Israel or en route, and who developed head or neck cancer, is now being financially compensated.

This law is extremely liberal. Because the average age of the irradiated population today is close to 50 years of age (ranging from 37 to 60), approximately two out of every three compensated persons would have contracted cancer even if not irradiated.

The difference in policy between this group and those employed in the nuclear industry is rooted in the working principle that unwilling and unknowing exposure to a deleterious agent must be compensated.

### Conclusion

Obviously, both models are schematic. In real life a third factor representing pressures—political, economic, or social—intervenes in the decision-making process. In the case of nuclear plants, the apparent benefit outweighs the potential harm. Economic pressures tilt in the direction of establishing the plant by minimizing the potential harm and applying adequate protective measures. Similarly, considering needs and resources, economic pressures push policy forward into effect unless strongly opposed by citizen groups.

By the same token, in the case of massive scalp irradiation of children for an essentially benign condition, overeagerness to treat promotes a positive vector when harm versus benefit is assessed. This notion probably affected the decision-making process at the time, to compensate for the lack of sufficient resources.

Both of these decisions were made almost 40 years ago. If one attempted to simulate a theoretical decision of this kind today, only one of the two (i.e., the one to start a nuclear plant) would survive, as economic powers opposition and strict radiation protection appears to minimize the risk. On the other hand, we know much more today about delayed risks of head irradiation to children in terms of cancer and brain damage (11–13).

Finally, the recent controversy with regard to commercial application of food irradiation may provide an appropriate up-to-date example and illustrate the general validity of our model. Food irradiation can retard spoilage and kill pathogenic bacteria without retaining radioactivity or changing texture, taste, and appearance. Nevertheless, pressures applied by environmental groups have delayed the full approval of this process by the U.S. Food and Drug Administration. Thus, in model terms we have a positive needs/positive resources/negative pressure situation. Furthermore, the balance of potential economic benefit versus minimal but potential harm (cancer risk to radiation workers) is strongly tilted by negative consumer pressures.

### REFERENCES

1. Modan B. Epidemiology and health policy: prevention initiatives, resource allocation, regulation and control. *Public Health Rep* 99:228–233 (1984).
2. Slovic P. Informing and educating the public about risk. *Risk Anal* 6:403–415 (1986).
3. Roman E, Beral V, Carpenter L, Watson A, Barton C, Ryder H, Aston DL. Childhood leukemia in the West Berkshire and Basingstoke and North Hampshire District Health Authorities in relation to nuclear establishments in the vicinity. *Br Med J* 294:597–602 (1987).

4. Gardner MJ, Hall AJ, Downes S, Terrell JD. Follow-up study of children born elsewhere but attending schools in Seascale, West Cumbria (schools cohort). *Br Med J* 295:819-822 (1987).
5. Gardner MJ, Hall AJ, Downes S, Terrell JD. Follow-up study of children born to mothers resident in Seascale, West Cumbria (birth cohort). *Br Med J* 295:822-827 (1987).
6. Gardner MJ, Hall AJ, Snee MP, Downes S, Powell CA, Terrell JD. Methods and basic data of case-control study of leukemia and lymphoma among young people near Sellafield nuclear plant in West Cumbria. *Br Med J* 300:429-434 (1990).
7. Viel JF, Richardson ST. Childhood leukemia around the La Hague nuclear waste reprocessing plant. *Br Med J* 300:580-581 (1990).
8. Urquhart JD, Black RJ, Muirhead MJ, Sharp L, Maxwell M, Eden OB, Jones DA. Case-control study of leukemia and non-Hodgkin's lymphoma in children in Caithness near the Dounreay nuclear installation. *Br Med J* 302:687-692 (1991).
9. Jablon S, Hrubec Z, Boice JD Jr, Stone BJ. *Cancer in Populations Living Near Nuclear Facilities*. Washington:U.S. Department of Health and Human Services, 1990.
10. Cook-Mozaffari P, Darby S, Doll R. Cancer near potential sites of nuclear installations. *Lancet* 2:1145-1147 (1989).
11. Modan B, Baidatz D, Mart H, Steinitz R, Levin SG. Radiation induced head and neck tumors. *Lancet* 1:277-279 (1974).
12. Ron E, Modan B, Boice JD Jr, Alfandary E, Stovall M, Chetrit A, Katz L. Tumors of the brain and nervous system after radiotherapy in childhood. *N Engl J Med* 319:1033-1039 (1988).
13. Modan B, Ron E, Werner A. Thyroid cancer following scalp irradiation. *Radiology* 123:741-744 (1977).
14. Modan B, Chetrit A, Alfandary E, Katz L. Increased risk of breast cancer following low dose irradiation. *Lancet* 1:629-631 (1989).